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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. | |
|-------------------|---------------|----------------------|---------------------|------------------|--|
| 10/722,184 | 11/25/2003 | Jeffrey O. Phillips | 03207556 | 7922 | |
| 26565 | 7590 | 04/09/2009 | EXAMINER | | |
| MAYER BROWN LLP | P.O. BOX 2828 | CHANG, CELIA C | | | |
| CHICAGO, IL 60690 | | ART UNIT | | PAPER NUMBER | |
| | | 1625 | | | |
| NOTIFICATION DATE | | DELIVERY MODE | | | |
| 04/09/2009 | | ELECTRONIC | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipdocket@mayerbrown.com

| | | | |
|------------------------------|------------------------|----------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/722,184 | PHILLIPS, JEFFREY O. | |
| | Examiner | Art Unit | |
| | Celia Chang | 1625 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 04 February 2009.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 151,156-181,183 and 185-272 is/are pending in the application.
 4a) Of the above claim(s) 171-173 and 211-272 is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 151,156,158,160,161,167-170,175-181,183 and 185-210 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>10/3/08</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

1. This is a RCE of SN 10/722,184.

Claims 1-150, 152-155, 157, 159, 162-166, 174, 182, 184 have been canceled. Claims 171-173, 211-272 stayed withdrawn from consideration. Claims 151, 156, 158, 160-161, 167-170, 175-181, 183, 185-210 are pending.

2. Claims 160-161 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is very confusing as to what does the terms “calcium buffering agent”, “magnesium buffering agent”...etc. are referring to. It is inconsistent between claim 160 and claim 161 because buffering agent ordinarily is referring to ionizable acid-base equilibrium which can maintain pH by shifting the reaction. A single salt such as calcium hydroxide or magnesium hydroxide has not been known to be able to perform any buffering capacity. It is unclear what is the scope of the claims. Is it the calcium hydroxide etc. of claim 161 when combined with another weak acid will give buffering activity of claim 160? Is it the salt calcium hydroxide etc. is the “further” element?

To the extend that the “buffering agent” of claim 160 are further element selected among the salts of claim 161, a 103(a) rejection will follow.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 160-161 are rejected under 35 U.S.C. 103(a) as being unpatentable over Taneja et al. US 2002/0192299 (recited on 5/26/06 IDS).

Please note that, claims 160-161 encompassed the composition of claim 151 and the further salt of carbonates when the carbonates are in equal molar to the sodium bicarbonate of the base claim.

Taneja et al. US 2002/0192299 disclosed PPI composition including omeprazole with a 1:1 molar ratio of bicarbonate/carbonate (see claim 1 and examples 3-4 on pages 5-6). Please note that the instant specification described composition of omeprazole and "0.2mEq to 5mEq bicarbonate per 2 mg PPI" and no limitation of the second buffering agent. The claim, however, included the second buffering agent which is in equal molar amount to the sodium bicarbonate, that is, the Taneja invention. However, no particular description or enablement was found for the specific 1:1 molar ratio. Please note that Taneja disclosed a specific species of the claimed genus. While the species anticipated the genus, the genus as disclosed by the instant specification lacks antecedent basis of the species. Therefore, Taneja is always prior art.

4. Claims 151, 156, 158, 160-161, 167-170, 175-181, 183, 185-210 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over US 6,689,885; 6,645,988; 6,489,346; 5,840,737 or US 7,399,772 or provisional rejection over the pending claims of SN 10/418,410.

The difference between the instant claims and the composition of the issued patents is the inclusion of a thickening agent in the instant composition. Adding thickening agent is routine practice in pharmaceutical formulation, thus, is *prima facie* obvious over the issued claims in absent of unexpected result.

The instant composition claims and the process of using the basic composition for treatment of gastric acid disorder claims of the issued patents or pending claims, although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are drawn to material being used in the issued claims or copending claims. The material and method of using the exact same material should be bind together to prevent unreasonable multiple harassment based on the decision of *In re Ochai*. This is a provisional obviousness-type double patenting rejection over the pending application 10/418,410, because the conflicting claims have not in fact been patented.

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Applicants provided statement that applicants will consider submitting a terminal disclaimer but without providing such disclaimer.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang, Ph. D. whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres, Ph. D., can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang
Apr. 2, 2009

*/Celia Chang/
Primary Examiner
Art Unit 1625*